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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 09 975,123     | 10 09 2001  | Susan M. Freier      | RTS-0253           | 3629            |

7590 08 26 2003

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Marlton, NJ 08053

EXAMINER

ZARA, JANE J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1635

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DATE MAILED 08 26 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

# Office Action Summary

Application No.  
09/975,123

Applicant(s)  
Freier

Examiner  
Jane Zara

Art Unit  
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 10, 2003
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-15, and 21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 13, 15, and 21 is/are rejected.
- 7) ☒ Claim(s) 2-10 and 14 is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are a) \_\_\_\_\_ accepted or b) \_\_\_\_\_ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) \_\_\_\_\_ approved b) \_\_\_\_\_ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some\* c) None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |  |
|--|--|
| 1. Notice of References Cited (PTO 802)                      | 4. Interview Summary (PTO 413) Paper Only          |
| 2. Notice of Transposition Patent Drawing Received (PTO 116) | 5. Notice of Informal Patent Application (PTO 152) |

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### **DETAILED ACTION**

This Office action is in response to the communication filed June 6, 2003, Paper No. 8.

Claims 1-10, 12-15 and 21 are pending in the instant application.

#### ***Response to Arguments and Amendments***

Any rejections not repeated in this Office action are hereby withdrawn

Applicant's arguments with respect to claims 1-10, 12-15 have been considered but are moot in view of the new ground(s) of rejection.

#### **New Grounds of Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 12, 13, 15 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the term "antisense compound" cannot be determined.

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 12, 13, 15 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to antisense compounds targeting insulin like growth factor binding protein 5. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between members of the genus is permitted. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the broad genus comprising compounds that target and inhibit the expression of insulin like growth factor binding protein 5. The specification and claims do not indicate the elements that are essential to the broad genera comprising antisense compounds that inhibit the target gene insulin like growth factor binding protein 5. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in the genus such that the common attributes or characteristics

conclude that the disclosure fails to provide a representative number of species to describe the

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genus claimed. Thus, Applicant was not in possession of the claimed genus comprising antisense compounds that target and inhibit insulin like growth factor binding protein 5.

***Allowable Subject Matter***

Claims 2-10, 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

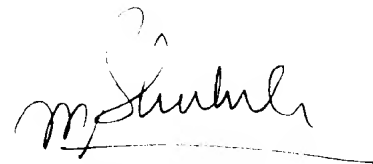
Applicant is advised that, if communication or earlier communications from the examiner reach the examiner by telephone are unsuccessful, the examiner's supervisor, John McGuyader, can

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be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'R. Shukla', with a horizontal line drawn underneath it.

**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

August 14, 2005